UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

ROBERT REID, on Behalf of Himself and All Others Similarly Situated,

Plaintiff - Appellant,

v.

JOHNSON & JOHNSON and MCNEIL NUTRITIONALS, LLC,

Defendants - Appellees.

No. 12-56726

D.C. No. 3:11-cv-01310-L-BLM
U.S. District Court for Southern California, San Diego

MANDATE

The judgment of this Court, entered March 13, 2015, takes effect this date.

This constitutes the formal mandate of this Court issued pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure.

FOR THE COURT:
Molly C. Dwyer
Clerk of Court

Jessica F. Flores
Deputy Clerk

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ROBERT REID, on Behalf of Himself and All Others Similarly Situated, *Plaintiff-Appellant*, v. JOHNSON & JOHNSON and MCNEIL NUTRITIONALS, LLC, *Defendants-Appellees*.	No. 12-56726 D.C. No. 3:11-cv-01310-L-BLM OPINION

Appeal from the United States District Court
for the Southern District of California
M. James Lorenz, Senior District Judge, Presiding

Argued and Submitted
June 5, 2014—Pasadena, California

Filed March 13, 2015

Before: Alex Kozinski, Stephen S. Trott,
and Consuelo M. Callahan, Circuit Judges.

Opinion by Judge Callahan

SUMMARY*

Standing / Preemption

The panel affirmed in part, and reversed in part, the district court's decision dismissing a false advertising lawsuit brought against Johnson & Johnson and McNeil Nutritionals, LLC, concerning assertions McNeil made about its product Benecol, a substitute for butter or margarine.

McNeil declared on Benecol's label that the product contained "No Trans Fat" because the amount of trans fat in Benecol was so insignificant that it was authorized under the Food and Drug Administration's regulations to make that statement. McNeil also contended that Benecol satisfied the standards set forth in a 2003 FDA letter that authorized its plant stanol esters statements, and was entitled to preemptive effect.

The panel held that the plaintiff-appellant had standing to challenge McNeil's statements. The panel also held that appellant's state law claims for relief were not preempted. Specifically, the panel held that appellant's claims were not preempted to the extent they were predicated on McNeil's trans fat statements. In addition, the panel declined to afford preemptive effect to agency actions that did not carry the force of law under *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001), and its progeny; and applying the rule, the panel held that the FDA's 2003 letter lacked preemptive effect. Finally, the panel held that appellant's action was not

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

barred by the primary jurisdiction doctrine, which allows courts to stay proceedings or dismiss a complaint without prejudice pending resolution of an issue within the special competence of an administrative agency. The panel remanded for further proceedings.

COUNSEL

Jack Fitzgerald (argued), Gregory S. Weston, and Melanie Persinger, The Weston Firm, San Diego, California; Ronald A. Marron and Beatrice Skye Resendes, The Law Offices of Ronald A. Marron, APLC, San Diego, California, for Plaintiff-Appellant.

Matthew I. Kaplan (argued), Mollie F. Benedict, and Amanda Villalobos, Tucker Ellis LLP, Los Angeles, California, for Defendants-Appellees.

OPINION

CALLAHAN, Circuit Judge:

Robert Reid appeals the district court's decision dismissing his false advertising lawsuit against Johnson & Johnson and McNeil Nutritionals, LLC (collectively, "McNeil"). Reid challenges a number of McNeil's assertions about its product, Benecol. Benecol is a vegetable oil-based spread that McNeil sells as a healthy substitute for butter or margarine. Among other things, on Benecol's label, McNeil prominently declares that the product contains "No Trans Fat" and contains plant stanol esters that lower cholesterol. Benecol, however, does contain trans fat. McNeil

nonetheless contends that the amount of trans fat in the product is so insignificant that it is authorized under the Food and Drug Administration's (FDA) regulations to make the statement. It is also undisputed that Benecol does not comply with the terms of the FDA's regulation authorizing plant stanol ester-based health claims. McNeil contends that Benecol nonetheless satisfies the standards set forth in a 2003 FDA letter that authorizes its plant stanol esters statements and is entitled to preemptive effect.

The district court found that Reid lacked standing to challenge the statements and that Reid's claims for relief were preempted. However, the district court rejected McNeil's arguments that Reid's action was barred by the primary jurisdiction and abstention doctrines. We conclude that Reid has standing, that Reid's claims for relief are not preempted, and that Reid's action is not barred by the primary jurisdiction doctrine. Accordingly, we reverse the district court's standing and preemption decisions, affirm the district court's decision not to invoke the primary jurisdiction doctrine, and remand for further proceedings.

I

A

McNeil manufactures and sells Benecol.[1] Benecol is manufactured with partially hydrogenated vegetable oil,

[1] The facts are drawn from Reid's complaint. *See Salameh v. Tarsadia Hotel*, 726 F.3d 1124, 1128 (9th Cir. 2013) ("Because the district court dismissed the complaint on the pleadings, the facts come from the second amended complaint, except where otherwise noted."), *cert. denied*, 134 S. Ct. 1322 (2014).

which contains artificial trans fat. According to Reid, "[a]rtificial trans fat does not exist in nature, and the human body has not evolved to digest it." It is "a toxic food additive that, in the amounts present in Benecol, negatively affects blood cholesterol levels."

Low density lipoprotein ("LDL"), or "bad" cholesterol, carries cholesterol to arteries and tissues. High density lipoprotein ("HDL"), or "good" cholesterol, "takes cholesterol *away* from tissues to the liver, where it is removed from the body." High levels of LDL cholesterol and low levels of HDL cholesterol are associated with an increased risk of heart disease. The consumption of artificial trans fat "increases 'bad' LDL cholesterol and decreases 'good' HDL cholesterol." Consequently, consuming partially hydrogenated vegetable oil "causes cardiovascular [] disease, diabetes and cancer."

Benecol also contains plant stanol esters. Consuming plant stanols has been shown to reduce LDL cholesterol and thus the risk of heart disease. According to Reid, the partially hydrogenated vegetable oil in Benecol counteracts any positive effect associated with plant stanol esters in the product.

The outside packaging for Benecol includes the following statements:

- "Proven to Reduce Cholesterol"
- "No Trans Fat"
- "No Trans Fatty Acids"

- "Use at least 2 servings of spread per day with your meals and snacks. Each serving contains 0.85 g of Plant Stanol Esters (0.5 g plant stanols). BENECOL® Spreads can help you meet the National Cholesterol Education Program Guidelines recommended amount of 2 g plant stanols/sterols per day."

- "Plant Stanol Esters, the unique ingredient found only in BENECOL® Spreads, are derived from natural plant components found in vegetable oils such as soy. Plant Stanol Esters [sic] proven ability to lower cholesterol is supported by ***over 25 studies***, including one reported in the New England Journal of Medicine."

- "Products containing 0.7 g or more of Plant Stanol Esters per serving eaten twice a day with meals for a daily intake of at least 1.4 g may reduce the risk of heart disease as part of a diet low in saturated fat and cholesterol. A serving of BENECOL® spread contains 0.85 g of Plant Stanol Esters."

The outer packing depicts several heart icons, and the packaging for Benecol Light spread also depicts vegetables. The interior packaging, which a consumer would not see unless he or she opened the package (presumably, after purchasing it), further states:

> The name BENECOL® brings together Bene, meaning "good" and col, for "cholesterol". BENECOL® offers you a great way to reduce your cholesterol with a delightfully good-tasting spread. Did you know that 2 or more servings of BENECOL® Spreads each day:
>
> ✓**Reduces** "bad" (LDL) cholesterol
>
> ✓**Reduces** total cholesterol
>
> ✓**Works** to further reduce cholesterol for those on cholesterol—lowering statin medications
>
> ✓**Blocks** cholesterol from being absorbed into your body

It also explains:

> How can BENECOL® Spreads have 0 grams trans fat if they contain partially hydrogenated oils?
>
> A small amount of partially hydrogenated oils are used in BENECOL® Spreads to maintain a semi-solid structure and to enhance the melting characteristics of the BENECOL® Regular Spread. As a result, BENECOL® Spreads[] contain an extremely low level of trans fat. The FDA allows foods containing less than 0.5 grams of trans fat/serving to be labeled 0 grams trans fat, since this is considered an insignificant amount.

Reid contends that he is a lay consumer with no background in nutrition or food science. He purchased Benecol at three different stores in California over a period of more than three years prior to filing the complaint. He asserts that he did so based on McNeil's representations in its advertisements and on its packaging. Benecol costs more than similar products, and Reid contends that he would not have been willing to pay as much as he did—if anything at all—for Benecol had he not been misled.

B

Reid filed his complaint on June 14, 2011. He alleged that McNeil's plant stanol esters-based health and "No Trans Fat" claims were not authorized under the FDA's regulations and were false. He further asserted that the "Proven to Reduce Cholesterol" and related statements were false and misleading and rendered Benecol an improperly marketed drug. He also contended that McNeil created Benecol's name and used heart graphics and vegetable depictions to reinforce its deceptive statements and to convey misleading information about Benecol's health benefits. He asserted claims for relief on behalf of a putative class of Benecol purchasers under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200–10; False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500–09; and Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750–84.

The district court granted McNeil's motion to dismiss. Initially, the district court decided that Reid had sufficiently alleged an economic injury, but lacked standing because he failed to plead reasonable reliance on any misrepresentations. The district court further concluded that Reid's claims for

relief were preempted under federal law. It held that McNeil's plant stanol esters statements complied with a 2003 FDA letter where the agency discussed its intentions about enforcing certain requirements for health claims about plant stanol esters, and it found that McNeil's cholesterol reduction and trans fat statements complied with FDA regulations. The court rejected McNeil's arguments that it should stay or dismiss the case under the primary jurisdiction or abstention doctrines. It also denied Reid's request to take judicial notice of a number of FDA warning letters. Reid appealed and we have jurisdiction pursuant to 28 U.S.C. § 1291.

II

We review de novo a district court's order granting a motion to dismiss on preemption grounds, for lack of standing, or for failure to state a claim upon which relief can be granted. *Lily v. ConAgra Foods, Inc.*, 743 F.3d 662, 664 (9th Cir. 2014) (preemption); *Mont. Shooting Sports Ass'n v. Holder*, 727 F.3d 975, 979 (9th Cir. 2013) (standing), *cert. denied*, 134 S. Ct. 955 (2014); *Henry A. v. Willden*, 678 F.3d 991, 998 (9th Cir. 2012) (failure to state a claim). We review the district court's "ultimate decision" to exercise or "decline to exercise jurisdiction for abuse of discretion, but conduct de novo review of the court's application of the primary jurisdiction doctrine." *N. Cnty. Commc'ns Corp. v. Cal. Catalog & Tech.*, 594 F.3d 1149, 1154 (9th Cir. 2010) (quoting *Rhoades v. Avon Prods., Inc.*, 504 F.3d 1151, 1162 n.11 (9th Cir. 2007)).

III

The district court appeared to dismiss Reid's claims for relief for lack of standing under California's standing

requirements for the UCL, FAL, and CLRA. To establish standing to bring a claim under these statutes, plaintiffs must meet an economic injury-in-fact requirement, which demands no more than the corresponding requirement under Article III of the U.S. Constitution. *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 (9th Cir. 2013). In a false advertising case, plaintiffs meet this requirement if they show that, by relying on a misrepresentation on a product label, they "paid more for a product than they otherwise would have paid, or bought it when they otherwise would not have done so." *Id.* at 1104 n.3, 1108; *see also POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014) ("A consumer who is hoodwinked into purchasing a disappointing product may well have an injury-in-fact cognizable under Article III . . . ."). Reid undoubtedly satisfied this individual reliance requirement, as he alleged that he would not have been willing to pay as much as he did for Benecol, if anything, if he had not been misled by McNeil's misrepresentations about Benecol's health effects.

The district court nevertheless decided Reid lacked standing because he failed to "set forth alleged facts showing that Benecol's statements may deceive a reasonable consumer." It is true that violations of the UCL, FAL, and CLRA are evaluated from the vantage point of a "reasonable consumer." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008). Under that test, a plaintiff must "show that members of the public are likely to be deceived." *Id.* (internal quotation marks omitted). But the reasonable consumer standard, unlike the individual reliance requirement described above, is not a standing requirement. Rather, it raises questions of fact that are appropriate for resolution on a motion to dismiss only in "rare situation[s]." *Id*. at 939.

Even if the district court intended to dismiss Reid's complaint for failure to state a claim upon which relief can be granted, it erred. The district court found that McNeil's "alleged misrepresentations would not likely deceive a reasonable consumer" in light of its disclosures on its ingredient list (i.e., the presence of partially hydrogenated vegetable oil). However, as we have previously stated: "We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception." *Williams*, 552 F.3d at 939. Regardless, it is far from clear that typical consumers understand that a product containing partially hydrogenated vegetable oil necessarily has trans fat, so even if an ingredient list has a curative effect in some cases, it might not here. Reid's allegations of misrepresentations are plausible enough to survive a motion to dismiss.

IV

The district court also found that Reid's claims for relief were preempted. The parties' arguments invoke express and conflict preemption. Express preemption exists when a statute explicitly addresses preemption. *See Chicanos Por La Causa, Inc. v. Napolitano*, 558 F.3d 856, 863 (9th Cir. 2009). Conflict preemption applies when it is impossible to comply with both federal and state law or when state laws stand as obstacles to accomplishing federal objectives. *See id*. As will be made clear, whether Reid's claims are preempted turns on our interpretation of the FDA's actions. The preemption analysis turns on whether the challenged statements are authorized by the FDA's regulations or other pronouncements of similar legal effect. *See Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 339–40 (3d Cir. 2009). Before analyzing the

statements at issue, we first set forth the statutory and regulatory framework.

A

The Nutritional Labeling and Education Act ("NLEA") amended the Food, Drug, and Cosmetic Act ("FDCA") to "establish[] uniform food labeling requirements, including the familiar and ubiquitous Nutrition Facts Panel found on most food packages." *Lily*, 743 F.3d at 664. The "NLEA also provides that no state may 'directly or indirectly establish any requirement for the labeling of food that is not identical' to the federal requirements." *Id.* at 664–65 (quoting 21 U.S.C. § 343-1(a)(5)) (ellipsis omitted). "The phrase 'not identical to' means 'that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food that are not imposed by or contained in the applicable federal regulation or differ from those specifically imposed by or contained in the applicable federal regulation.'" *Id.* at 665 (quoting 21 C.F.R. § 100.1(c)(4)) (alteration marks omitted). The NLEA also provides, however, that it does not preempt any state law unless the law is "expressly preempted."[2] *Holk*, 575 F.3d at 337–38. The NLEA does not preempt state law-based causes of action that are identical to the federal labeling requirements. *See POM Wonderful*, 134 S. Ct. at 2238 ("[B]y taking care to mandate express preemption of *some* state laws, Congress if anything indicated that it did not intend the FDCA to preclude requirements arising from other sources." (emphasis added)); *Farm Raised Salmon Cases*, 175 P.3d 1170, 1178–84 (Cal. 2008).

[2] Other federal laws, however, may still preempt labeling claims. *See Holk*, 575 F.3d at 336 & n.4.

Under the FDA regulations, the general rule is that "nutrient content claims" are not permitted on food labels. Nutrient content claims are statements that "expressly or implicitly characterize[] the level of a nutrient." 21 C.F.R. § 101.13(b). However, the regulations do authorize some nutrient content claims. These include statements about the amount or percentage of a nutrient that are consistent with the labeling regulations (e.g., "less than 3 g of fat per serving"), similar statements that include a disclaimer (e.g., "only 200 mg of sodium per serving, not a low sodium food"), or statements that do not characterize the level of nutrient and are not false or misleading (e.g., "100 calories"). *Id.* § 101.13(i). For authorized nutrient content claims, statements may use "[r]easonable variations in the spelling of terms . . . and their synonyms" provided that they "are not misleading (e.g., 'hi' or 'lo')." *Id.* § 101.13(b)(4).

In addition to regulating nutrient content claims, FDA regulations require labels to include the familiar "Nutrition Facts" box, dubbed the "nutrition label" by federal regulations. Companies are required to disclose information about the presence of specified nutrients in this label. *Id.* § 101.9(c). Though the nutrition label clearly contains information about nutrient content, the claims made in it are not considered "nutrient content claims" for the purposes of FDA regulations. *See id.* § 101.13(c). While a required statement inside a nutrition label escapes regulations reserved for nutrient content claims, the identical statement outside of the nutrition label is still considered a nutrient content claim and is therefore subject to section 101.13. As a result, a requirement to state certain facts in the nutrition label is not a license to make that statement elsewhere on the product.

FDA regulations specifically address trans fat. They provide that trans fat should generally be disclosed in the nutrition label "except that label declaration of trans fat content information is not required for products that contain less than 0.5 grams of total fat in a serving if no claims are made about fat, fatty acid or cholesterol content." *Id.* § 101.9(c)(2)(ii). The regulation further provides:

> If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. Except as provided for [under the provisions allowing for simplified format labeling], if a statement of the trans fat content is not required and, as a result, not declared, the statement "Not a significant source of trans fat" shall be placed at the bottom of the table of nutrient values.

Id.

Outside the nutrition label, claimants may make nutrient content claims such as "fat free," "no fat," "zero fat," or "negligible source of fat" on labels where the food contains less than 0.5 grams of fat per serving and certain other conditions are met. *Id.* § 101.62(b). There is a parallel regulation permitting similar claims about "saturated fat," *see id.* § 101.62(c), but not about "trans fat." The FDA considered authorizing a "trans fat free" claim but decided not to enact the regulation in light of "insufficient scientific information." *See* Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, Health Claims, 68 Fed. Reg. 41,434, 41,464–65 (July 11, 2003).

In addition to nutrient content claims, the FDA has specifically authorized some health claims. *See* 21 C.F.R. § 101.14. Such claims, however, must be "complete, truthful, and not misleading." *Id.* § 101.14(d)(2)(iii). These specifically include plant stanol esters health claims. *Id.* § 101.83. The applicable regulation states:

> A health claim associating diets that include plant sterol/stanol esters with reduced risk of heart disease may be made on the label or labeling of a food . . . provided that . . . [t]he claim states that diets that include plant sterol/stanol esters "may" or "might" reduce the risk of heart disease [and] . . . [t]he claim specifies the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of [coronary heart disease or "CHD"] and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of plant sterol and stanol esters that have been associated with reduced risk of [CHD] are . . . 3.4 g or more per day of plant stanol esters. . . . The claim [must also specify] that the daily dietary intake of plant sterol or stanol esters should be consumed in two servings eaten at different times of the day with other foods.

Id. § 101.83(c)(2). The claim may also "state that the relationship between intake of diets that include plant sterol/stanol esters and reduced risk of heart disease is through the intermediate link of 'blood cholesterol' or 'blood total and LDL cholesterol.'" *Id.* § 101.83(d)(2). The

regulations further provide that the authorization only applies to foods that meet the 1.7 grams/serving threshold (i.e., two servings amounting to 3.4 grams) and "contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition." *Id.* §§ 101.83(c)(2)(iii)(A)(2), (D), 101.14(e)(6).

In 2003, the FDA issued a letter in response to a request from Cargill Health & Food Technologies that the FDA state its intention not to enforce certain requirements of the plant stanol esters regulation. In the letter, the FDA indicated that it "will consider exercising enforcement discretion with regard to the use of a claim about reduced risk of CHD in the labeling of phystosterol containing food" that did not meet the requirements in the regulation. Among other things, the FDA also indicated that qualifying health claims had to relate to foods containing 400 mg per serving, had to specify "that the daily dietary intake of phytosterols that may reduce the risk of CHD is 800 milligrams (mg) or more per day," and the food had to satisfy the regulation's other requirements (suchas the 10 percent nutrient requirement). *See id.* § 101.83(c)(2)(iii)(B)–(D).

The FDA has also recognized that "a heart symbol" can constitute a health claim. *Id.* § 101.14(a)(1). Where a health claim is authorized and "where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material." *Id.* § 101.14(d)(2)(iv). Most health claims based on the benefits of consuming the substance "must specify the daily dietary intake necessary to achieve the

claimed effect, as established in the regulation authorizing the claim." *Id.* § 101.14(d)(2)(vii). Health claims must also conform "to all specific provisions in the appropriate section." *Id.* § 101.14(e)(2).

B

The challenged statements can be grouped into two categories: (1) trans fat nutrient content claims; and (2) plant stanol esters-based health claims.[3]

1

The preemption analysis of the "No Trans Fat" claim turns on whether the statement is authorized by FDA

regulations. These regulations create two categories of nutrient content claims, "expressed" and "implied," imposing a different set of requirements for each type of claim. 21 C.F.R. § 101.13(b)(1)–(2). The "No Trans Fat" claim is an expressed claim because it "is [a] direct statement about the level . . . of [trans fat] in the food." *Id.* § 101.13(b)(1). FDA regulations authorize expressed claims that "do[] not in any way implicitly characterize the level of the nutrient in the food and [are] not false or misleading in any respect (e.g., '100 calories' or '5 grams of fat')." *See id.* § 101.13(i)(3).

[3] Reid also challenges McNeil's use of various symbols on Benecol's label. McNeil's ability to use these symbols depends on its authority to make the trans fat nutrient content claims and plant stanol esters-based health claims. Because we find that none of Reid's other claims are preempted, his challenges to these symbols also survive. Furthermore, Reid acknowledges that his contention that Benecol is a misbranded cholesterol drug is only viable "[a]bsent regulatory allowance," meaning that it also rises or falls with his other health claims.

The FDA has provided guidance about whether a "No Trans Fat" nutrient content claim is permissible for products containing small amounts of trans fat. In one of its warning letters,[4] the FDA indicated that "No Trans Fat" is "an unauthorized nutrient content claim . . . which has not been defined by FDA." The agency noted that the letter's recipient could "make a truthful statement on a product's label that specifies the amount of *trans* fat per serving." *See* 21 C.F.R. § 101.13(i). In a second letter, the FDA similarly indicated that "trans fat-free" is an "unauthorized nutrient content claim." We defer to the FDA's interpretation of its own rules, even if the product of an informal and non-final process,[5] unless its interpretation is clearly erroneous. *See Pub. Lands for the People, Inc. v. U.S. Dep't of Agric.*, 697 F.3d 1192, 1199 (9th Cir. 2012) ("Where an agency interprets its own regulation, even if through an informal process, its interpretation of an ambiguous regulation is

[4] Reid argues that the district court erred by failing to take judicial notice of the warning letters and that we should take judicial notice of the letters. Judicial notice, however, is unnecessary for materials establishing the legal principles governing a case. *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010); *see also Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1073 (E.D. Cal. 2010) (considering FDA warning letters for the purposes of a motion to dismiss). Accordingly, it is not necessary for us to take judicial notice of the warning letters in order to consider them. Because we do consider the letters, it is also unnecessary for us to determine whether the district court erred by failing to do so.

[5] The FDA uses warning letters, among other enforcement measures, to police objectionable food and beverage labels in lieu of a preapproval process. *POM Wonderful*, 134 S. Ct. at 2239. Although "informal and advisory," the FDA issues warning letters to obtain voluntary and prompt corrective action for what it considers to be significant violations of the FDCA. The warning letters are publicly available on the FDA's website.

controlling under *Auer* [*v. Robbins*, 519 U.S. 452, 461 (1997),] unless plainly erroneous or inconsistent with the regulation." (internal citations and alteration marks omitted)), *cert. denied*, 133 S. Ct. 1464 (2013).

A nutrient content claim fails if it is "false or misleading in *any* respect." 21 C.F.R. § 101.13(i)(3) (emphasis added). Because Benecol contains *some* trans fat (between 0 and 0.5 grams per serving), its "No Trans Fat" claim is misleading in at least one respect. The structure of FDA labeling regulations bolsters this conclusion. As noted, under section 101.62(b)–(c), the FDA has expressly allowed "No Fat" and "No Saturated Fat" claims for products that contain less than 0.5 grams of fat or saturated fat per serving. By contrast, the FDA explicitly decided *not* to authorize a "No Trans Fat" claim in light of a lack of scientific information. *See* 68 Fed. Reg. 41,434, 41,464–65. If a "No Trans Fat" claim is not "false or misleading" under 21 C.F.R. § 101.13 (i)(3), a "No Fat" or "No Saturated Fat" claim cannot be treated differently. This would mean that section 101.62(b)–(c) is redundant: If section 101.13(i)(3) authorizes "No Fat" and "No Saturated Fat" claims for products with small amounts of fat or saturated fat, then why would the FDA go to the trouble of promulgating a separate regulation expressly allowing these claims? It would be incongruous to have the same rule for both "No Fat"/"No Saturated Fat" and "No Trans Fat" claims, as the former is expressly permitted while the latter is not due to a lack of scientific consensus about the dangers of trans fat. Thus, the FDA's reading of section 101.13(i)(3)—that the regulation does not authorize "No Trans Fat" claims—makes the most sense of the overall labeling regime, as it gives meaning to section 101.62(b)–(c).

McNeil says its "No Trans Fat" claim is the equivalent of its statement on the nutrition label that Benecol contains 0 grams of trans fat per serving, a statement it must make under section 101.9(c)(2)(ii). FDA regulations allow a label to include synonyms of authorized nutrient content claims, *id.* § 101.13(b)(4), which McNeil claims is exactly what its "No Trans Fat" claim is. But, as noted, claims required on a nutrition label under section 101.9(c), like Benecol's "0 grams trans fat per serving" claim, are not nutrient content claims and thus are not covered by section 101.13(b)(4)'s synonym rule. That McNeil must say Benecol contains 0 grams of trans fat per serving on its nutrition label makes no difference here.

The district court found that "No Trans Fat" was not misleading, as any reasonable consumer would infer that Benecol contains trans fat, given that partially hydrogenated vegetable oil is disclosed as an ingredient. As noted, however, there is no reason to believe that consumers understand that partially hydrogenated vegetable oil contains trans fat. Consequently, we conclude that Reid's claims for relief are not preempted to the extent they are predicated on McNeil's trans fat statements.

2

As for the plant stanol esters and cholesterol reduction claims, McNeil admits that the claims fall short of 21 C.F.R. § 101.83(c)(2), which permits health claims related to plant stanol esters that meet certain requirements. These health claims do, however, meet the criteria described in the FDA's 2003 letter about its enforcement intentions. McNeil argues that, in spite of its noncompliance with section 101.83(c)(2), the 2003 letter "created [a] federal policy preempting state

law." We must decide whether this letter is entitled to preemptive effect.[6]

The Supremacy Clause gives federal authorities the power to preempt state law by declaring that the "Constitution, and the Laws of the United States . . . [are] the supreme Law of the Land." U.S. Const. art. VI, cl. 2. "The phrase 'Laws of the United States' encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization." *City of New York v. FCC*, 486 U.S. 57, 63 (1988). Thus, "a federal agency acting within the scope of its congressionally delegated authority may . . . render unenforceable state or local laws that are otherwise not inconsistent with federal law." *Id*. at 64 (internal quotation marks omitted). Because the Supremacy Clause privileges only "[l]aws of the United States," an agency pronouncement must have the force and effect of federal law to have preemptive force. *See Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 245 (3d Cir. 2008); *Wabash Valley Power Ass'n, Inc. v. Rural Electrification Admin.*, 988 F.2d 1480, 1485–86 (7th Cir. 1993). Beyond the constitutional text, there is nothing to guide us in determining whether an agency action creates "law" for Supremacy Clause purposes.

[6] Although Reid suggests that the cholesterol reduction claims are not authorized even if the 2003 letter is entitled to preemptive force, the FDA explicitly found that "[t]he scientific evidence establishes that including plant sterol/stanol esters in the diet helps lower blood total and LDL cholesterol levels." 21 C.F.R. § 101.83(b)(2). Thus, it appears that if Benecol contains the minimum amounts necessary to make the health claims at issue, it is consequently also proven to reduce cholesterol as far as the FDA is concerned.

The Supreme Court has created a framework for deciding whether Congress contemplated that a particular agency pronouncement would have the force and effect of federal law in the *Chevron* context. Under *Chevron*, when an agency fills a gap in a statute that Congress explicitly or implicitly left open for that agency to fill, its "regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984). In other words, it's the agency's job—not ours—to fill with "law" the statutory interstices Congress left open. We intervene only when in doing so the agency has acted unreasonably, exceeded the authority Congress delegated to it, or failed to observe required procedures. But only those agency pronouncements that Congress intended to carry the "force of law" require *Chevron*-level deference, and we determine whether an agency spoke with such force under the standard set forth in *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001), and its progeny.

We conclude that this standard is pertinent to the preemption analysis here. In both *Chevron* and preemption contexts, a central inquiry is whether an agency has validly created federal law pursuant to the gap-filling power delegated to it by Congress. In the former situation, we decide whether *Chevron*-level deference is due because Congress intended for the agency's pronouncement to carry the force of law; in the latter, we decide whether state law is preempted because Congress intended for the agency's pronouncement to carry the binding and exclusive force of federal law. Creation of federal law should demand at least the same formality for purposes of preemption as it does for

purposes of *Chevron* deference.[7] We therefore join the Third Circuit in declining to afford preemptive effect to agency actions that do not carry the force of law under *Mead* and its progeny. *See Fellner*, 539 F.3d at 245.

Applying this rule here, the 2003 letter lacks preemptive effect. While some agency actions short of notice-and-comment rulemaking may have the force of law, "enforcement guidelines" like those set forth in the FDA's letter "are beyond the *Chevron* pale." *Mead*, 533 U.S. at 234.

To begin, the letter itself does not indicate that the FDA "set out with a lawmaking pretense in mind." *Id*. at 233. The letter is couched in tentative and non-committal terms. The letter does not promise that the FDA will not enforce its existing regulation applicable to health claims about plant stanol esters. Instead, the letter provides that the FDA "intends to consider the exercise of enforcement discretion" in certain circumstances. The FDA has separately stated, however, that such letters indicate that it "does not intend to object to the use of the claim specified in the letter, provided that the products that bear the claim are consistent with the stated criteria." Thus, the FDA appears to regard the letter as providing firmer guidance regarding its own enforcement discretion than the 2003 letter's tentative language would suggest. Still, the letter's plain language does not authorize any health claims that conflict with the FDA's existing plant stanol esters rule. The letter only expresses the FDA's

[7] We do not reach the question of how "the presumption against preemption," and the federalism concerns that animate it, might further guide our evaluation of the preemptive effect of an action by the FDA implementing the FDCA. *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

"intent" to "consider" enforcement discretion while the FDA continues deliberations regarding whether a change to that rule is appropriate. The FDA's equivocal language regarding its intention to foreclose its own ability to enforce non-compliance with existing rules is a good indication that it did not intend to foreclose state law challenges to health claims that do not comply with existing rules.

Reading the FDA's 2003 letter in the context of the FDCA's statutory scheme also militates against a finding of preemption. The FDA can approve health claims effective immediately, pending consideration of public comment and publication of a final regulation. 21 U.S.C. § 343(r)(7). In fact, the FDA issued its 2000 plant stanol esters rule pursuant to this authority, and thereby approved of certain health claims about plant stanol esters effective immediately. Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease, 65 Fed. Reg. 54,686, 54,713–54,714 (Sept. 8, 2000). The fact that the FDA did not invoke this authority in setting forth the enforcement criteria in the 2003 letter also indicates that the FDA did not intend to issue a standard with the force of law that would foreclose the public protections under state law food labeling and false advertising claims.

Similarly, we are not convinced that Congress intended for an FDA pronouncement like that set forth in the 2003 letter to have the binding and exclusive effect of federal law. Giving the 2003 letter preemptive effect would effectively open an additional shortcut allowing the FDA to authorize health claims without notice and comment. Shortcuts are not inherently bad and, again, some agency actions short of notice-and-comment rulemaking may have the binding and exclusive force of federal law. But Congress demonstrated

that it knew how to create such a shortcut in enacting 21 U.S.C. § 343(r)(7), indicating that Congress did not intend to create an additional, unstated means of rulemaking by way of letters tentatively stating the FDA's enforcement discretion.

Finally, while not determinative of our decision, we are concerned that allowing the FDA effectively to authorize health claims by way of statements of its enforcement policy could place those authorizations beyond judicial review. This is so because agency decisions not to take enforcement action are usually committed to agency discretion by law and thus generally not subject to judicial review under the Administrative Procedure Act. *See* 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 828–35 (1985). Foreclosing challenges to, and judicial review of, the FDA's health claim approvals likely would not serve Congress's goals in the FDCA of increasing the protections of public health and safety. *See POM Wonderful*, 134 S. Ct. at 2234 ("The FDCA statutory regime is designed primarily to protect the health and safety of the public at large."). Indeed, Congress was careful to preserve judicial review of the FDA's actions even where the FDA makes a proposed regulation effective immediately, pending consideration of public comment and publication of a final regulation. 21 U.S.C. § 343 (r)(7) ("Such proposed regulations shall be deemed final agency action for purposes of judicial review.").

For these reasons, we hold that Reid's claims for relief are not preempted by the FDA's 2003 enforcement letter. We note that this conclusion, of course, in no way indicates that Reid's state law claims have merit.

V

McNeil also asserts that the district court erred by rejecting its argument that Reid's action is barred by the primary jurisdiction doctrine. McNeil argues that the primary jurisdiction doctrine applies here because "FDA expertise is required to resolve the question of whether Benecol contains sufficient plant stanol esters to reduce cholesterol and whether the insignificant amount of trans fats undermine the positive impact of plant stanol esters." McNeil further suggests that the FDA is in the process of an "ongoing regulatory review" pending the completion of its final plant stanol esters rule.

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). It "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *GCB Commc'ns, Inc. v. U.S. S. Commc'ns, Inc.*, 650 F.3d 1257, 1263–64 (9th Cir. 2011) (internal quotation marks omitted). "It is useful . . . in instances where the federal courts do have jurisdiction over an issue, but decide that a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.* at 1264 (internal quotation marks omitted). It applies in "limited circumstances" and is "not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit." *Clark*, 523 F.3d at 1114 (internal quotation marks omitted).

McNeil's argument has some facial appeal because the preemption issues in this case turn on the interpretation and applicability of the FDA's regulations and other actions. Nonetheless, the argument is ultimately unpersuasive. The FDA has already addressed some issues that McNeil identifies as requiring further regulatory review. For example, the FDA has specifically declined to authorize "No Trans Fat" nutrient content claims, and has issued warning letters to companies making such claims.

Reid's claims present no issues of first impression, as the FDA has already addressed the substantive issues raised here. Regarding plant stanol esters, there is already an interim final rule on the books. Plus, it has been over a decade since the FDA indicated that it would issue a new final plant stanol esters rule.[8] *Cf. Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 692 (3d Cir. 2011) (concluding that there was little risk of inconsistent rulings that would support the application of the primary jurisdiction doctrine where the agency had not issued any rulings for several years). Similarly, there is no indication that the FDA is contemplating authorizing "No Trans Fat" statements.[9] The issue that this case ultimately

[8] Any final rule might not govern the preemption analysis for the time period covered by Reid's action. *See Elim Church of God v. Harris*, 722 F.3d 1137, 1141–42 (9th Cir. 2013).

[9] The FDA has shown no signs of backing away from its determination that "trans fat free" nutrient content claims are not authorized. It stated:

> Since 2003, both controlled trials and observational human studies published on trans fatty acid consumption have consistently confirmed the adverse effects of trans fatty acid consumption on intermediary risk factors (e.g., serum lipoproteins) and the increased risk of CHD . . . . [Several notable] expert panels all

turns on is whether a reasonable consumer would be misled by McNeil's marketing, which the district courts have reasonably concluded they are competent to address in similar cases. *See, e.g.*, *Chacanaca*, 752 F. Supp. 2d at 1124.

The "deciding factor" in determining whether the primary jurisdiction doctrine should apply is "efficiency." *Rhoades v. Avon Prods., Inc.*, 504 F.3d 1151, 1165 (9th Cir. 2007). Because the FDA has made considered judgments on the legal issues in this case, we reject McNeil's argument. *See id*. Consequently, the district court properly declined to dismiss or stay the case pursuant to the primary jurisdiction doctrine.

VI

McNeil further argues that Reid's action is barred by California's judicial abstention doctrine. *See Alvarado v. Selma Convalescent Hosp.*, 153 Cal. App. 4th 1292, 1297–1303 (2007). Having dismissed Reid's claims on preemption grounds, the district court never addressed this issue. We therefore leave it for the district court's consideration on remand.

> concluded that there is no threshold intake level for industrially-produced trans fat that would not increase an individual's risk of CHD, or adverse effects on risk factors for CHD. Moreover, the panels also agree that trans fatty acids have a stronger effect on the risk of CHD than saturated fatty acids.

Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169, 67,172 (Nov. 8, 2013). Accordingly, the FDA has tentatively concluded that there is no scientific consensus that partially hydrogenated oils, as the primary dietary source of artificial trans fat, are safe for use in food. *See id.* at 67,173.

VII

Reid's basic contention in this case is that Benecol is improperly being marketed and sold to consumers as health food. At this early stage of the proceedings, we cannot say whether he is right or wrong. It is clear, however, that Benecol's label prominently states that Benecol contains "No Trans Fat." That statement is not true. Although Benecol may contain a relatively small amount of trans fat per serving, the FDA found that the existing scientific evidence was not sufficient for it to approve "No Trans Fat" claims. Despite this finding, McNeil made such a claim. Given that the FDA has indicated in warning letters that claims like "No Trans Fat" are not authorized, McNeil cannot shield itself from liability with the FDA's regulations. We also hold that an FDA letter stating a tentative enforcement policy does not preempt state law. Consequently, we reverse the district court's decision dismissing Reid's action. We affirm the district court's decision to the extent that it declined to invoke the primary jurisdiction doctrine. We remand for further proceedings consistent with this opinion.

AFFIRMED in part, REVERSED in part, and REMANDED.

Parties shall bear their own costs.